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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/199,129
Filing Date: November 24, 1998
Appellant(s): BYRUM ET AL.

BYRUM et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/31/05 appealing from the Office action mailed 5/31/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

An amendment to the specification to correct the continuity data in the first line of the specification was submitted after the mail date of the Final Rejection. In response to the After-Final amendment to the specification, the amendment was entered, and an Advisory Action was mailed stating that the amendment to the specification filed 6/07/05 apparently crossed the Final Rejection mailed 5/31/05 in the mail.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 4-12 stand rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and/or substantial utility or a well-established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

> "Credible Utility" - Where an Appellant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the Appellant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).
>
> "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of

the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

> "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

Claims 4-12 are drawn to a transformed plant comprising SEQ ID NO: 1 or complement thereof, and a method of using SEQ ID NO: 1 or complement thereof, in a method for determining a level or pattern in a plant. SEQ ID NO: 1, or complement thereof, is described in the specification as filed as an EST isolated from soybean leaf tissue. Appellants assert a general utility for the ESTs disclosed in the specification as filed, which includes SEQ ID NO: 1 through SEQ ID NO: 5521, as useful in the isolation of agronomically significant genes, as well as generic uses such as antibody production, gene expression probe, marker, etc. (See the specification as filed beginning with page 30, for a description of the various potential uses of the nucleic acid agents of the instant invention). The application does not disclose a utility specific for a nucleic acid comprising SEQ ID NO: 1 or a specific utility or activity for a protein or fragment encoded by a nucleic acid encoding SEQ ID NO: 1, nor does it disclose a specific utility for any full length gene which could be isolated using SEQ ID NO: I. Furthermore, there is no disclosed phenotype associated with the claimed transformed plant comprising SEQ ID NO: 1 or complement thereof, nor is there is any specific protein described

wherein SEQ ID NO: 1 or its complement can be used to determine the level or pattern of expression of said protein in a plant.

The nucleic acid molecule according to SEQ ID NO: 1 or complement thereof, is not supported by a specific asserted utility because the disclosed uses of the nucleic acids of the invention (and proteins encoded by said nucleic acids) are not specific and are generally applicable to any nucleic acid and/or protein. The specification states that the nucleic acid compounds of the invention (SEQ ID NO: 1 through 5521) may be useful as probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages.

Similarly, the specification as filed teaches that that proteins encoded by the nucleic acid molecules of the invention may be used for detection of expression, antibody production, Western blots, etc. These uses are also non-specific that are applicable to nucleic acids and/or proteins in general and are not particular or specific to the nucleic acids (and proteins encoded by said nucleic acids) being claimed.

Furthermore, the nucleic acid molecule according to SEQ ID NO: 1, or complement thereof, is not supported by a substantial utility, because no substantial utility has been established for the claimed subject matter. For example, the specification as filed teaches at page 30, beginning at line 10, that the nucleic acid molecules and fragments thereof of the present invention may be employed to obtain

other nucleic acid molecules. At page 32, lines 5-6 it states that the ESTs of the present invention can be used in methods of chromosome walking and inverse PCR to obtain promoter sequences and other genetic elements, and at lines 10-12, it states that the ESTs can be used to identify other cDNAs whose analogous genes contain promoters with desirable (i.e. undefined) expression patterns. The specification essentially describes the potential use of the nucleic acid molecules (ESTs) of the invention in further research to functionally characterize and isolated other nucleic acids. The need for such research clearly indicates that the nucleic acid molecule according to SEQ ID NO: 1, or complement thereof, the protein it encodes, or a transformed plant comprising said nucleic acid molecule and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the disclosed nucleic acid molecules (in particular SEQ ID NO: 1), or the proteins that are to be produced as final products resulting from processes involving the nucleic acid molecules of the claimed invention, have specific or substantial utilities. The research contemplated by Appellants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, since there is no disclosed phenotype associated with the claimed transformed plant comprising SEQ ID NO: 1, and no known function for the protein produced or encoded by SEQ ID NO: 1,

there is no real world context of use for the claimed transformed plant, and furthermore there is no substantial utility for the claimed invention. Moreover, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed.

Because there is no specific or substantial utility for a nucleic acid comprising SEQ ID NO: I (as discussed above), there is also no specific or substantial utility for a plant comprising a nucleic acid comprising SEQ ID NO: 1, or its complement, nor is there any specific utility for methods of determining the level or pattern of a protein which has no specific utility using SEQ ID NO: 1 or its complement. In the instant case, the specification does not disclose or provide any evidence that points to a specific or substantial biologically significant activity for nucleic acid comprising SEQ ID NO: 1, a plant comprising said nucleic acid, or a method of identifying an unknown protein, such that another non-asserted utility would be well established. Additionally, there is no art of record that discloses or provides any evidence that points to an activity for SEQ ID NO: 1 or its corresponding full length cDNA or the proteins that might be obtained using the full length cDNA to be obtained, such that another non-asserted utility would be well established.

Claim Rejections - 35 USC § 112-Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4-12 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Description

5. Claims 4-12 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

The claims are drawn to a transformed plant comprising a structural nucleic acid molecule *comprising* a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof, and a method of using a marker nucleic acid which specifically hybridize to a nucleic acid molecule *having* the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 or complement thereof.

The specification as filed, see pages 19-22, teaches that the nucleic acid molecules of the present invention are more specifically EST nucleic acid molecules or nucleic acid fragment molecules thereof. Therefore the nucleic acid molecule consisting

of SEQ ID NO: 1 is also interpreted as an EST nucleic acid molecule or a nucleic acid fragment molecule thereof. Moreover, the instantly claimed invention requires nucleic acid molecules *comprising* or *having* SEQ ID NO: 1 or complement thereof. The instantly claimed invention is drawn to a genus which includes any nucleic acid which minimally contains SEQ ID NO: 1 or complement thereof. The claim encompasses genes, full open reading frames, fusion constructs, and cDNAs. There is substantial variability among the species of DNAs encompassed within the cope of the claims because SEQ ID NO: 1 or complement thereof, is only a fragment of any full-length gene of cDNA species. The nucleic acids described in the specification as filed are not representative of the genus nucleic acids comprising SEQ ID NO: 1 or complement thereof. Furthermore, one of skill in the art would conclude that Appellant was not in possession of the claimed "nucleic acids comprising SEQ ID NO: 1 or complement thereof" because the specification as filed clearly indicates that further experimentation is required to identify the full scope of genetic elements encompassed by the instant claimed, see for example the specification as filed at pages 30-40.

Moreover, 1) the partial structure of the DNAs that comprise SEQ ID NO: 1 or complement thereof; 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs; 3) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the Appellant was in possession of the genus of DNAs which comprise SEQ ID NO: 1, or complement thereof. Thus, the specification

does not adequately provide a written description for nucleic acids comprising SEQ ID NO: 1 or complement thereof.

Appellants are directed to the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An Appellant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that Appellant was in possession of the claimed invention."

As stated above "[A]n Appellant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." In the instant case, since Appellants must perform further experimentation to identify the full scope of nucleic acid sequences comprising SEQ ID NO: 1 encompassed by the instant claims, and the full scope of transformed plants

encompassed by the claims, and the method of use comprising the use of the full scope of nucleic acid acids comprising SEQ ID NO: 1, Appellants have not provided sufficient evidence that Appellants were in possession of the full scope of the claimed invention as of the filing date of the instant application. Moreover, since further experimentation is required to describe the full scope of the claimed invention, Appellant's invention was not "ready for patenting" or sufficiently reduced to practice at the time of filing of the instant invention. Therefore, contrary to Appellant's assertions, Appellants were not in possession of the full scope of the claimed invention at the time of filing.

(10) Response to Argument

Provided is a summary of Appellants Position (see pages 4-5 of Appeal Brief 10-31-05):

A. Summary of Appellants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility ... where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed transformed plants and methods that, in their current form, provide at least one specific benefit to the public, for example, use of the transformed plants in a breeding program. This benefit is specific, and it is a "real world" or substantial benefit. Because the claimed plants and methods provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed plants and methods for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has likewise been met.

Furthermore, Applicants have provided an adequate description of the plants and methods that demonstrates Applicants' possession of the claimed invention. Each genus of nucleic acid molecule in the claimed plants and methods, *e.g.*, transformed plants comprising the nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1, for example, has been described by the recitation of a common structural feature – the nucleotide sequence of SEQ ID NO: 1 – which distinguishes plants having molecules within the genus from plants having molecules outside of the genus. Because the specification demonstrates that Applicants have possession of (and have provided an adequate description of) the claimed plants and methods, the specification satisfies the written description requirement of 35 U.S.C. § 112.

Claim Rejections - 35 USC § 101/112, 1st paragraph

6. Claims 4-12 stand rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and/or substantial utility or a well-established utility.

(Section **(B.)** of Appellant's arguments are addressed here:)

Appellant's arguments have been fully considered but they are not persuasive. Appellants traverse the instant rejection for the reasons set forth in the above summary. In particular Appellants argue that they have met their burden to provide at least one specific benefit to the public, particularly the transformed plants can be used in a breeding program. Moreover, Appellants argue that the Examiner misstates the nature of the asserted uses, ignores disclosed utilities and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* Appellants again asserted that the specification teaches the immediate benefits of the claimed transgenic plants and methods provide clear and immediate benefits, for example, use to follow a plant through breading program (*specification at page 18, lines 18-19, page 56, lines 15 through page 75, line 10, as cited by Appellants),* and to determine the level or pattern of expression of a protein or mRNA associate with that nucleic acid molecule. According to Appellants, either of these utilities described alone is enough to satisfy 35 USC § 101, and the rejection should be reversed. Appellants further provide a detailed general description setting forth how a nucleic acid molecule can be used in the preparation of (a) transgenic plant for use in breeding programs, (b) methods for determining a level or pattern in a plant cell, or plant tissue of a protein in a plant, wherein said method comprises (c) using *in situ* –hybridization, or (d) tissue printing.

Response:

The examiner agrees that the claimed transformed plants comprising a nucleic acid molecule comprising SEQ ID NO: 1 can be used in a breeding program, and furthermore that the nucleic acid molecule according to SEQ ID NO: 1 can potentially be used to determine a level or pattern of a protein potentially encoded by SEQ ID NO: 1. However, contrary to Appellant's assertions, the above uses described above cannot be considered either "specific" or "substantial" utilities as per the definitions provided in the REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS [published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000, and effective as of January 5, 2001.] namely:

> "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.
>
> "Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.
>
> On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

The asserted use of the claimed transformed plants and methods, described by Appellants above, can be applied to a broad class of the claimed invention, namely to each 5522 nucleic acid molecules, fragments thereof, and complements thereof, as disclosed in the specification as filed. Therefore the recited use cannot be considered specific to a nucleic acid molecule comprising or having SEQ ID NO: 1 or complement thereof, a transformed plant comprising said nucleic acid molecule, or to a method for identifying an unknown protein comprising the use of said nucleic acid molecules.

Additionally, in regards to the use of the claimed nucleic acid to determine a level or pattern of a protein potentially encoded by SEQ ID NO: 1, does not constitute a substantial utility. As stated above, "[A] Method of assaying for or identifying a material that itself has no "specific and/or substantial utility," do not define a substantial utility. Therefore, contrary to Appellant's assertions, the asserted utilities described above, do not constitute specific or substantial utilities as required and defined in the REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS [published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000, and effective as of January 5, 2001.]

Moreover, in regards to the immediate benefit for using the claimed transformed plants in a breeding program as a research tool, see pages 11-12, and page 14, 1st paragraph of Appellant's Brief, Appellants further argued: "[T]here can be no question that one skilled in the art can use the claimed transgenic plants and methods in a manner which provides an immediate benefit to the public, for example to easily identify progeny of interest in a breeding program. The detection of transgenic plants provides an immediate benefit to the public because, e.g., it enables a plant breeder to more efficiently allocate resources to progeny plants having a given genetic profile. This information about a plant's genetic profile, like the information about a compounds pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public."

Contrary to Appellant's assertions, apart from further refinement and development the skilled artisan could not appreciate the benefit (*See Brenner, 383 U.S. at 534, 148 USPQ at 695)* of using the claimed invention in a breeding program or using the claimed methods to identify the expression of level of an unknown protein. The specification does not provide any immediate and specific benefit, of transforming a plant comprising using any of the 5,521 nucleic acid molecules disclosed in the specification, or more specifically a nucleic acid molecule comprising SEQ ID NO: 1, or complement thereof, in a breeding program. There is no evidence or expectation of successfully using SEQ ID NO: 1 to identify progeny of a transgenic plant. There is no evidence that the transformed sequence would be expressed in the progeny at a detectable level such that it could be observed by *in situ* hybridization. As stated above,

without further refinement and development the skilled artisan would not be able to appreciate the immediate benefit of one of 5,521 nucleic acid molecules in a plant breeding program.

Appellants compared of the utility of the nucleic acid molecules of invention as a potential research tool, to other research tools such as a microscope, gas chromatographs, screening assays, and nucleotide sequencing. Contrary to Appellants assertions, not every utility will satisfy § 101, even if the utility is shared by a class of inventions. While a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy § 101. In the instant case, Appellant's disclosure of SEQ ID NO: 1 is provided with a laundry list of other nucleic acid molecules, each one of which can be potentially useful for the same purpose, namely in a transformed plant for use in breeding programs, or for use in a method for identifying an unknown protein. However, there is no disclosure specifically defining how to use SEQ ID NO: 1 or complements or fragments or sequences comprising SEQ ID NO: 1, in any specific manner. The generality of the disclosure as it pertains to the ***Uses of the Agents of the Invention*** (starting at page 30 of the specification as filed), is applicable to 5521 distinct nucleic acid sequences, homologues thereof, fragments thereof, complements thereof, and sequences comprising said sequences. Based upon this observation alone, it can be concluded that the asserted utility of the claimed invention is not *specific, and* that further research is required to identify a specific utility for the claimed invention.

Appellant's Conclusory Statement regarding Utility (page 15, last two paragraphs):

Appellants argued that they have explicitly identified specific and substantial utilities, not only in the specification, but in Appellant's responses. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result.....To date, the Examiner has provided no evidence that the claimed plants and methods would not work for the asserted utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn. In view of the Above, Appellants contend that the claimed plants, and methods are supported by credible, specific, and substantial utilities disclosed in the specification."

Response:

In response to Appellant's arguments, the examiner agrees that in order to violate 35 USC § 101, a claimed invention must be totally incapable of achieving a useful result. However, contrary to Appellant's assertions, they have asserted multiple uses, but they have not provided any evidence that the results produced from these multiple potential uses would actually prove to be a truly "useful result." The basic *quid pro quo* of the patent system requires disclosure of an invention having substantial utility. Appellant's disclosure in this case does not provide a *specific benefit in currently available form*, and therefore lacks substantial utility as required by 35 USC § 101.

As per MPEP § 2107[R-3], Deficiencies under the "useful invention" requirement of 35 U.S.C. 101 will arise in one of two forms. The first is where it is not apparent why the invention is "useful." This can occur when an applicant fails to identify any specific

and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966); In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible. In the instant case, as stated above, due to the generality of the asserted utilities of the nucleic acid molecules of the present invention, transgenic plants comprising said nucleic acid molecules, and methods of using said nucleic acid molecules to identify the expression of an unknown protein, taken together with the numerous nucleic acid molecules encompassed by the invention, it is concluded that instant invention as originally filed failed to identify any *specific* and *substantial* utility for the claimed transformed plants comprising a nucleic acid molecule comprising SEQ ID NO: 1, or methods of using a nucleic acid molecule having SEQ ID NO: 1 in a method to identify an unknown protein.

(Section **(C.)** of Appellant's arguments are addressed here:)

7. Claims 4-12 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Appellants assert that the instant rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that

"the enablement requirement is met if the description enables any mode of making and using the invention." Moreover, Appellants assert, unless and until the examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper.

Response

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

The breadth of the claimed invention encompasses transformed plants comprising nucleic acid molecules comprising many structural variants, wherein said nucleic acid molecules encode a protein of unknown function and effect on the transformed plant. The specification as filed describes 5,521 distinct nucleic acid molecules, and provides a generic description as how to use these sequences.

Contrary, to Appellant's assertions, Appellants have not disclosed how to use the transformed plants, and/or methods according to the present invention. The specification as filed describes 5,521 distinct nucleic acid molecules, however there is no specific guidelines provided in the specification as filed that would teach the skilled artisan how to use the full scope of the claimed invention without undue experimentation.

The amount of experimentation required to practice the claimed invention would require: further experimentation to identify the full length cDNA, and furthermore to identify the claimed transformed plant comprising the structural nucleic acid molecule "comprising" SEQ ID NO: 1 or its complement, at the time of filing of the instant invention the person of ordinary skill in the art would not accept that the recited or disclosed plant was currently available for any beneficial or practical use. Moreover, since the biological activity of the full length cDNA potentially identified by using SEQ ID NO: 1 was not known, further experimentation is required to identify the biological activity associated with the full length cDNA, and the protein it encodes, in order for the skilled artisan to recognize how to use the claimed transformed plants. Additionally, in

regards to the claimed methods for determining a level or pattern of a protein in a plant comprising the use of a marker nucleic acid which specifically hybridizes to a nucleic acid molecule having (comprising) SEQ ID NO: 1 or complement, it is apparent that further experimentation would be required first to identify the full length cDNA comprising SEQ ID NO: 1, isolate the protein encoded by the full length cDNA, and furthermore identify the biological activity of the encoded protein. Once the biological activity of the protein is identified, the skilled artisan would be able to identify a real-world context of use for the claimed methods. Without identifying the biological activity of the encoded protein, the skilled artisan would not be able to recognize the real-world context of use of the claimed method, therefore it is apparent that at the time of the instant invention the person of ordinary skill in the art would not accept that the recited or disclosed plant was currently available for a particular use.

Therefore, absent evidence to the contrary, Applicants have not provided any specific guidelines that would teach the skilled artisan how to make and use the full scope of the claimed invention without undue experimentation.

(Section **(D.)** of Appellant's arguments are addressed here:)

8. Claims 4-12 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

9. Appellant's arguments have been fully considered but are not persuasive. Appellants traverse the instant rejection on the grounds that a person of ordinary skill in the art would, after reading the present specification, understand that Appellants had possession of transgenic plants and methods employing nucleic acid molecules comprising or specifically hybridizing to a nucleic acid sequence of SEQ ID NO: 1. (See also, pages 16-19 of the Appeal Brief).

Response

Contrary to Applicant's assertions, the breadth of the instant claims are directed to plants transformed with nucleic acids encompassing full length gene sequences (i.e. gene sequences yet to be discovered) and cDNAs comprising SEQ ID NO: 1, sequences that hybridize to SEQ ID NO: 1, and methods which utilize said sequences. However, none of these sequences meet the written description provision of 35 USC 112, first paragraph. For example, a cDNA comprising a partial sequence, as claimed, encompasses a wide variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region, however, the specification does not disclose an open reading frame for SEQ ID NO: 1 and, therefore, would not be representative of the breadth of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. In the instant case, the specification discloses only a single common structural feature shared by the claimed genus, i.e. SEQ ID NO: 1, and this disclosed structural feature does not constitute a substantial portion of the claimed genus, since there is no coding region disclosed as

being associated with this sequence. The specification provides insufficient written description to support the genus encompassed by the claims.

Furthermore, Appellants argue at page 19 of the Appeal Brief, that:

> "If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the rcited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such-it either contains the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Similarly, if a nucleic acid molecule specifically hybridizes to the nucleic acid sequence of SEQ IDNO: 1, then it is a member of the genus of nucleic acid molecules recited in claim 8."

Contrary to Applicant's assertions, at the time of filing, the full scope of the claimed invention was not sufficiently reduced to practice such that the skilled artisan would recognized that Applicants were in possession of the full scope of the claimed invention. "[A]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." In the instant case, Applicants must perform further experimentation in order to identify the full scope of nucleic acid sequences comprising SEQ ID NO: 1 encompassed by the instant claims, including the nucleic acid sequence of the structural genes encompassed by claim 4, which encompasses promoter sequences, intron sequences, 5' and 3' UTR sequences, comprised within the full scope of transformed plants encompassed by the claims, and the method of use comprising the use of the full scope of nucleic acid acids hybridizing to SEQ ID NO: 1. Applicants have not provided sufficient evidence that Applicants were in possession of the full scope of the claimed invention as of the filing date of the instant application. Moreover, since further

experimentation is required to describe the full scope of the claimed invention, Applicant's invention was not "ready for patenting" or sufficiently reduced to practice at the time of filing of the instant invention. Therefore, contrary to Applicant's assertions, Applicants were not in possession of the full scope of the claimed invention at the time of filing.

Moreover, 1) the partial structure of the nucleic acid molecules that comprise SEQ ID NO: 1 or complement thereof, or sequences which hybridize to said nucleic acid molecules; 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs; 3) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of nucleic acid molecules which comprise SEQ ID NO: 1, or complement thereof, or sequence which hybridizes to said molecules. Thus, the specification does not adequately provide a written description for transgenic plants comprising nucleic acids comprising SEQ ID NO: 1 or complement thereof, or methods comprising the use of nucleic acids which hybridize to nucleic acids comprising SEQ ID NO: 1 or complement thereof.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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